MAY 1 6 2002

K021024

Section 3
HemosIL High Abnormal Control - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

Contact Person:

Carol Marble, Regulatory Affairs Manager
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

March 28, 2002

Name of the Device(s):

HemosIL High Abnormal Control ASSAYED

HemosIL High Abnormal Control 3 UNASSAYED

Classification Name(s):

Common Name:	Plasma Coagulation Control
Product Code:	81GGN
Regulation Number:	21 CFR 864.5425
Classification:	Class II

Identification of Predicate Device(s):

510(k) No.	Predicate Device(s)	Analytes
K931118	Assess™ High Abnormal Control	Prothrombin Time (PT) Activated Partial Thromboplastin (APTT)
K864271	IL Test™ Abnormal Chromogenic Control Plasma Level 2	Antithrombin
K912711	IL Test™ Protein C Control Plasma (component of IL Test™ ProClot kit)	Protein C
K930327	IL Test™ Protein S Control Plasma (component of IL Test™ Protein S kit)	Protein S

Description of the Device/Intended Use(s):

Available as an assayed high abnormal control (HemosIL High Abnormal Control) or unassayed high abnormal control (HemosIL High Abnormal Control 3), the product is intended for the quality control of coagulation assays in the high abnormal range on IL Coagulation and ELECTRA™ Systems. The High Abnormal Control is prepared using human citrated plasma from healthy donors (not heparinized plasma or plasma samples under oral anticoagulant therapy) and modified, by means of a dedicated process, to simulate an abnormal coagulation sample.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

HemosIL High Abnormal Control is substantially equivalent to the predicate devices in performance, intended use and safety and effectiveness for the specific claimed analyte.

Section 3 (Cont.)
HemosIL High Abnormal Control - 510(k) Summary
(Summary of Safety and Effectiveness)

Summary of Performance Data:

A precision study was performed with HemosIL High Abnormal Control over multiple days with multiple runs using specific lots of reagents and control:

Analyte	n=	Mean	Within-Run %CV
Activated Partial Thromboplastin (APTT) (Seconds)	80	64.4	2.62
Antithrombin (% Activity)	80	22.8	9.90
Protein C (% Activity)	80	14.4	6.11
Protein S (% Activity)	40	29.5	2.75
Prothrombin Time (PT) (Seconds)	80	43.6	1.61

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 6 2002

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, Massachusetts 02421-3125

Re: k021024
Trade/Device Name: HemosIL High Abnormal Control ASSAYED
HemosIL High Abnormal Control 3 UNASSAYED
Regulation Number: 21 CFR § 864.5425
Regulation Name: Plasma, Coagulation Control
Regulatory Class: II
Product Code: GGN
Dated: March 28, 2002
Received: March 29, 2002

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K021024

Device Names: HemosIL High Abnormal Control ASSAYED

Indications for Use:

HemosIL High Abnormal Control ASSAYED is intended for the quality control of coagulation assays in the high abnormal range on IL Coagulation and ELECTRA™ Systems. The High Abnormal Control is prepared using human citrated plasma from healthy donors (not heparinized plasma or plasma samples under oral anticoagulant therapy) and modified to simulate an abnormal coagulation sample.

Values for all analytes are in the high abnormal range.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021024

✓ Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)